



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

November 24, 2004

**FILE COPY**

Dr. Elaine Jones  
Mr. William M. Zoffer  
GlaxoSmithKline  
PO Box 13398  
Research Triangle Park, North Carolina 27709

Dear Dr. Jones and Mr. Zoffer:

Your petition requesting the Food and Drug Administration to refrain from approving any ANDA for a fluticasone propionate nasal spray unless the product is shown to meet the same standards of products quality as Flonase<sup>®</sup>, was received by this office on 11/23/2004. It was assigned docket number 2004P-0523/CP 1 and it was filed on 11/24/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler, Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2004P-0523

ACK 1